UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,458	07/17/2003	Baback Gharizadeh		3111

44955 7590 07/11/2007

SQUIRE, SANDERS & DEMPSEY L.L.P.
1 MARITIME PLAZA, SUITE 300
SAN FRANCISCO, CA 94111

EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,458	GHARIZADEH, BABACK	
	Examiner	Art Unit	
	Christopher M. Babic	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 11, 2007 has been entered. Claim(s) 1-12 are pending.

New Grounds of Claim Rejections - 35 USC § 112 - 2nd Paragraph

The rejections of claim(s) 5-12 as set forth in the Office Action dated December 11, 2006 have been withdrawn in view of Applicant's amendments.

The following new ground(s) of rejection is made in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite because it is unclear how the unspecific amplification products are typed by DNA sequencing, if the sequencing primers **do not** anneal to the unspecific amplification products. Appropriate clarification of required.

New Grounds of Claim Rejections - 35 USC § 102

The rejections of claim(s) 1-12 over Rady as set forth in the Office Action dated December 11, 2006 have been withdrawn in view of Applicant's amendments and accompanying evidence within the affidavit filed April 11, 2007.

Response to Arguments

Applicant's arguments have been fully considered but they are moot in view of the new grounds of rejection presented below.

The following new grounds of rejections are made in view of Applicant's amendments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim(s) 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tully et al. (WO 96/06187; 29 February 1996).

With regard to claim(s) 1, Tully teaches methods of multiplex sequencing utilizing sequencing primers comprising a mobility identifier (abstract; pg. 5 and 6, for example). Specifically, Tully teaches methods comprising the steps of: (a) providing a sample containing nucleic acid molecules (middle pg. 2, Tully teaches samples with one or more types; middle pg. 10, Tully teaches their methods as useful for screening for microorganisms, for example); (b) providing a mixed pool of at least two **structurally different** sequencing oligonucleotide primers, whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or close to the target or variable region (middle-end pg. 5, Tully teaches the use of multiple sequencing primers comprising a mobility identifier, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (middle pg. 2, Tully teaches multiplex sequencing, for example); (d) determining the type, species or target region to which the primer or primers have hybridized by extending the hybridized primer or primers in a DNA sequencing reaction (middle pg. 5, Tully teaches determining different sequencing with PAGE, for example).

With regard to claim(s) 2, Tully teaches sequencing utilizing multiple labeled ddNTPs (middle pg. 3, for example).

With regard to claim(s) 3, Tully teaches their methods as useful for screening for microorganisms (middle pg. 10, for example).

With regard to claim(s) 4 and 5, Tully teaches samples with one or more types (middle pg. 2, for example).

2. Claim(s) 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ye et al. ("Fluorescent microsphere-based readout technology for multiplexed human single nucleotide polymorphism analysis and bacterial identification" Hum Mutat. 2001 Apr;17(4):305-16).

With regard to claim(s) 1, Ye teaches methods of multiplex sequencing utilizing sequencing primers comprising a unique zipcode sequences (abstract; fig. 1, for example). Specifically, Ye teaches methods comprising the steps of: (a) providing a sample containing nucleic acid molecules (pg. 307, col. 2, Ye teaches amplification of 16S rDNA from multiple bacterial species, for example); (b) providing a mixed pool of at least two **structurally different** sequencing oligonucleotide primers, whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or close to the target or variable region (pg. 308, col. 1, Ye teaches ASPE reactions

as outlined in fig. 1, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (pg. 308, col. 1, Ye teaches ASPE reactions as outlined in fig. 1, for example); (d) determining the type, species or target region to which the primer or primers have hybridized by extending the hybridized primer or primers in a DNA sequencing reaction (pg. 309, col. 1, Ye teaches flow cytometric analysis, for example).

With regard to claim(s) 2, Ye teaches ASPE reactions as outlined in fig. 1 (pg. 308, col. 1, for example).

With regard to claim(s) 3-5, Ye teaches amplification of 16S rDNA from multiple bacterial species, for example (pg. 307, col. 2, for example).

New Grounds of Claim Rejections - 35 USC § 103

The following new grounds of rejections are made in view of Applicant's amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim(s) 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tully et al. (WO 96/06187; 29 February 1996) in view of Rady et al. ("Type-specific primer-mediated direct sequencing of consensus primer-generated PCR amplicons of human papillomaviruses: a new approach for the simultaneous detection of multiple viral type infections. J Virol Methods. 1995 Jun;53(2-3):245-54").

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach sequencing of HPV.

With regard to claim(s) 6-10, Rady provides a supporting disclosure that teaches the amplification of a conserved region within multiple different HPV types and subsequent sequencing with sequence specific primers (page 246-249, materials and methods; fig. 1, for example).

With regard to claim(s) 11, the sequencing of low yield amplification of fragments is inherent to the methods of Tully.

With regard to claim(s) 12, due to the indefiniteness of the claim (see above 112, 2nd section), the teachings of Tully appear to anticipate the intended limitations of the instant claims. The primers of Tully are designed to anneal to unspecific amplification products.

2. Claim(s) 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al. ("Fluorescent microsphere-based readout

technology for multiplexed human single nucleotide polymorphism analysis and bacterial identification" Hum Mutat. 2001 Apr;17(4):305-16) in view of Rady et al. ("Type-specific primer-mediated direct sequencing of consensus primer-generated PCR amplicons of human papillomaviruses: a new approach for the simultaneous detection of multiple viral type infections. J Virol Methods. 1995 Jun;53(2-3):245-54").

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach sequencing of HPV.

With regard to claim(s) 6-10, Rady provides a supporting disclosure that teaches the amplification of a conserved region within multiple different HPV types and subsequent sequencing with sequence specific primers (page 246-249, materials and methods; fig. 1, for example).

With regard to claim(s) 11, the sequencing of low yield amplification of fragments is inherent to the methods of Ye.

With regard to claim(s) 12, due to the indefiniteness of the claim (see above 112, 2nd section), the teachings of Ye appear to anticipate the intended limitations of the instant claims. The primers of Ye are designed to anneal to unspecific amplification products.

Conclusion

Claim(s) 1-12 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7/7/07

Christopher M. Babic

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600